# STATE OF CONNECTICUT
## DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

October 2, 2018

Mr. Andrew Agwunobi, Administrator
John Dempsey Hospital
263 Farmington Avenue
Farmington, CT 06032

Dear Mr. Agwunobi:

Unannounced visits were made to John Dempsey Hospital that concluded on September 6 and 7, 2018 by a representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation with additional information received through September 7, 2018.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which was/were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

**The plan of correction is to be submitted to the Department by October 16, 2018.**

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) The date each such corrective measure or change by the institution is effective;

(3) The institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) The title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by October 10, 2018 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

An office conference has been scheduled for **October 19, 2018 at 10:00am i**n the Facility Licensing and Investigations

DATES OF VISIT: September 6 and 7, 2018

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Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Heidi Caron, MSN, RN, BC, CLNC
Supervising Nurse Consultant
Facility Licensing and Investigations Section

HAC:mb

Complaint: CT#23812

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (f) Diagnostic and therapeutic and/or (i)

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General (6).

1. Based on review of facility policies,, review of facility documentation, review of facility meeting minutes and interviews, the facility failed to ensure that the radiology data and/or issues were incorporated in the hospital-wide QAPI (Quality Assurance Performance Improvement) Committee. The finding includes:
   a. Review of facility documentation sent to the hospital by the DEEP (Department of Energy and Environmental Protection) dated 7/16/18 identified that the Hospital did not maintain accurate records of radiation exposure for all occupationally exposed radiation workers and monitoring records exceeded quarterly periodicity (reports for 5/2016 through March 2018 were reviewed).
   Review of radiation safety meeting minutes dated 5/19/16 identified that the DEEP had identified that too many dosimetry badges were being returned by staff unused. Review of Radiation Safety meeting minutes dated 8/15/16 noted emails were sent to individuals who did not return their badge and email messages were being sent to the Supervisors' of individuals who were not responding to the emails. Review of quarterly radiation safety meeting minutes dated 11/17/16 through 5/30/18 indicated, in part, that dosimetry badges were worn incorrectly and/or reported on as an on-going issue. Review of the Hospital QAPI meeting minutes dated 5/2016 through 8/2018 with the Compliance Officer on 9/7/18 at 11:38 AM identified that the QAPI committee convened on a monthly basis and radiation QA measures/ improvement guidelines were only discussed during the QAPI meeting dated 11/21/17. In addition, the data presented at the QAPI meeting dated 11/21/17 lacked documentation of the ongoing issue regarding the dosimetry badges.
   Interview with the Chief Quality Officer on 9/6/18 at 1:20 PM noted that the Department of Radiation reported to the Hospital Quality Committee in 2017 but, had no set reporting schedule.
   Interview with the Associate Vice President for Research on 9/6/18 at 2:08 PM indicated that he/she was not made aware of the ongoing dosimetry issues until 5/2017, and ongoing systemic issues should have been taking care of. Further interview identified that it was an identifiable gap that the Radiation Department did not report regularly to the hospital- wide QAPI Committee.
   The Hospital QAPI Committee Charter identified a purpose to oversee QI initiatives in all areas of the Hospital functions and processes. The Charter further identified, in part, responsibilities to measure, analyze and track quality indicators and monitor performance improvement project status.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (f) Diagnostic and therapeutic and/or (i) General (6).

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2. Based on medical record review, review of facility radiation documentation, review of facility policies and interviews the facility failed to ensure that radiation policies were comprehensive. The finding includes:
   a. Review of facility documentation sent to the hospital by the DEEP (Department of Energy and Environmental Protection) dated 7/16/18 identified that the Hospital did not maintain accurate records of radiation exposure for all occupationally exposed radiation workers and monitoring records exceeded quarterly periodicity (reports for 5/2016 through March 2018 were reviewed). Review of radiation safety meeting minutes dated 5/19/16 identified that DEEP had identified that too many dosimetry badges were being returned by staff unused. Review of quarterly radiation safety meeting minutes dated 11/16/17, 2/27/18, 5/30/18 indicated, in part, dosimetry badges were worn incorrectly by physicians. On 9/6/18 and 9/7/18, a review of staff dosimetry reports for IR (interventional radiology) and the cardiac catheterization lab during the period of 5/1/18 through 7/31/18 identified that dosimetry badges, to include to include a minimum of a chest and collar badge per staff member were to be read on a monthly basis for all appropriate personnel. The review further identified that multiple staff failed to return badges and/or had negligible readings on badges returned.
   Observation on 9/6/18 at 11:00 AM noted that Medical Resident #1 was performing fluoroscopy procedures in the Fluoroscopy department and had donned a thyroid collar and apron for lead protection. The observation further indicated that although Medical Resident #1 had a dosimetry badge attached to his/her thyroid collar, he/she denied having a chest badge beneath the apron nor was a badge observed.
   Interview with Medical Resident #1 at this time identified that he/she was not aware if he/she was issued two badges and a second badge for Medical Resident #1 was not observed in the container of badges.
   Interview with the RSO (Radiation Safety Officer) on 9/6/18 identified that the dosimetry records included multiple negligible dosimetry badge readings (less than 2 millirem) and most likely reflected that badges were not being worn. Further interview with the RSO on 9/7/18 at 9:05 AM noted, in part that staff in the fluoroscopy room, cardiac catheterization lab and IR are required to wear 2 badges. The RSO further noted that one badge is to be worn on the outside of the collar and the other badge is to be worn under the apron at the chest or waist level.
   The hospital policy for personal radiation dosimetry identified that dosimeters must be placed on the front of the body from the waist to the upper chest and to call the Office of Radiation Safety for proper placement for other circumstances (i.e. an individual is wearing a lead apron). The policy did not provide direction for badge placement when the use of two dosimetry badges was required. The hospital job description for RSO identified a duty to develop, recommend, implement and monitor the Radiation Safety Program's standards, policies and procedures in accordance with regulations.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (f) Diagnostic and therapeutic and/or (i) General (6).

3. Based on a review of facility documentation, review of facility policies, review of facility observations and interviews, the facility failed to ensure that radiation exposure was

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appropriately monitored. The finding includes:

a. A review of dosimetry reports from 5/2016 through March of 2018 identified a large number of discrepancies.
Each months dosimetry report showed many badges turned in a month or two late. In addition, badges that would show 'unused' for several months and then a higher than normal reading that might indicate a user had perhaps worn one badge for several months while the others were turned in unused.
Review of radiation safety meeting minutes dated 5/19/16 identified that the DEEP had identified that too many dosimetry badges were being returned by staff unused. Review of quarterly radiation safety meeting minutes dated 11/16/17, 2/27/18, 5/30/18 indicated, in part, dosimetry badges were worn incorrectly by physicians.
Review of staff dosimetry reports for IR (interventional radiology) and the cardiac catheterization lab during the period of 5/1/18 through 7/31/18 identified that dosimetry badges, to include a minimum of a chest and collar badge per staff member were to be read on a monthly basis for all appropriate personnel. Further review further identified that multiple staff failed to return badges and/or had negligible readings on badges returned.
Review of credential files and/or facility training logs and/or the list of Medical Residents who worked in Interventional Radiology or the Cardiac Cath Lab indicated that 1 of 5 of these Medical Resident's (Medical Resident #2) lacked documentation for radiation safety training.
Observation on 9/6/18 at 11:00 AM noted that Medical Resident #1 was performing fluoroscopy procedures in the Fluoroscopy department and had donned a thyroid collar and apron for lead protection. Further observation indicated that although Medical Resident #1 had a dosimetry badge attached to his/her thyroid collar, he/she denied having a chest badge beneath the apron nor was a badge observed.
Interview with the RSO (Radiation Safety Officer) on 9/6/18 identified that the dosimetry records included multiple negligible dosimetry badge readings (less than 2 millirem) and most likely reflected that badges were not being worn.
Interview with the Radiology Department's Administrative Assistant II on 9/6/18 at 12:00 PM noted that the RSO (Radiation Safety Officer) received all dosimetry badge collection reports. Further interview with the Radiology Department's Administrative Assistant II on 9/6/18 at 3:40 PM indicated that he/she did not have a method to track Medical Resident-issued dosimetry badges until recently (5/2018).

The facility policy for personal radiation safety identified that all personnel who are working in the ionizing radiation area must wear Dosimetry. The policy noted that Dosimetry must be exchanged and returned by the end of the first week of each month. The hospital job description for RSO included responsibilities to monitor radiation safety programs and identify safety issues and initiate, recommend and/or provide corrective action and implementation of corrective action.

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